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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,103	09/25/2003	Thomas M. Soukup	P-9328.01	6342
7590 03/09/2005				
Elisabeth L. Belden Medtronic Inc. 7000 Central Ave., N.E. Mailstop B408 Minneapolis, MN 55432			EXAMINER MULLEN, KRISTEN DROESCH	
			ART UNIT 3762	PAPER NUMBER
DATE MAILED: 03/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/671,103	SOUKUP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/27/04 (IDS).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-56,58,59 and 61-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-56,58,59 and 61-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/27/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 50-54, and 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Owens et al. (4,972,846).

With respect to claim 50, Owens shows a system including a defibrillation electrode (gold plating) comprising a first layer of porous PTFE (14) adjacent to at least one surface of the defibrillation electrode having a fibril length adapted to bleed gas away from the surface of the defibrillation electrode (Col. 3, lines 46-51), a second PTFE layer (12) formed over the first PTFE layer and having a fibril length adapted to prevent substantially all tissue in-growth (Col. 3, lines 11-32).

Regarding claims 51-52, Owens shows the first and second layers comprise expanded PTFE.

With respect to claims 53, 63 and 64, Owens shows the first layer (14) has a pore size greater than or equal to 50 microns, or between 50 and 100 microns and a thickness greater than or equal to 50 microns (Col. 3, lines 46-51),

Regarding claim 54, Owens shows the second layer (12) has a pore size less than or equal to 10 microns (Col. 3, lines 11-32).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 55 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owens (4,972,846) as applied to claim 50 and further in view of Carson (5,931,862). Owens is as explained before. However, Owens shows an epicardial electrode to be placed on the outer surface of the heart. Attention is directed to Carson which shows it is well known to provide a coil defibrillation electrode adapted for placement in the heart, and further shows it is known to cover such an electrode with tubular e-PTFE. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the defibrillation electrode structure of Owens to the well known coil defibrillation electrode structure and further modify the first and second PTFE layers of Owens to a tubular configuration to cover the now modified well known coil defibrillation electrode since it is well known in the art to provide coil defibrillation electrodes with tubular e-PTFE covering.

5. Claims 56, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owens (4,972,846) as applied to claim 50 and further in view of Soukup et al. (5,609,622). Owens is as explained before. However, Owens shows an epicardial electrode to be placed on the outer surface of the heart. Attention is directed to Soukup which shows it is well known to provide a coil defibrillation electrode adapted for placement in the heart, and further shows it is known to cover such an electrode with e-PTFE tape. Therefore, it would have been obvious to one with

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ordinary skill in the art at the time the invention was made to modify the defibrillation electrode structure of Owens to the well known coil defibrillation electrode structure and further modify the first and second PTFE layers of Owens to a tubular configuration to cover the now modified well known coil defibrillation electrode since it is well known in the art to provide coil defibrillation electrodes with e-PTFE tape covering.

6. Claims 58, 66, 68, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owens (4,972,846) as applied to claim 50 and further in view of Hirschberg (4,573,480).

Regarding claims 58, 66, and 68, Owens is as explained before. Owens fails to show a third layer having a fibril length adapted to selectively promote tissue in-growth. Hirschberg teaches applying additional porous ePTFE onto an impervious PTFE layer of a defibrillation electrode in order to allow for tissue ingrowth in the vicinity of an electrode to prevent dislocations (Col. 2, lines 45-55). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the system of Owens by adding porous ePTFE onto the impervious PTFE layer of Owens in order to allow a defibrillation electrode in order to allow for tissue ingrowth in the vicinity of an electrode to prevent dislocations.

With respect to claim 69, Hirschberg further show the third layer is longitudinally offset from the second layer.

7. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owens (4,972,846) in view of Hirschberg (4,573,480) as applied to claim 58, and further in view of McCarthy (6,406,420). Owens and Hirschberg are as explained before. Owens and Hirschberg fail to teach the specific pore size utilized for promoting tissue ingrowth is between 20 and 50 microns. McCarthy teaches the specific pore size dimensions that are desirable for promoting

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tissue ingrowth include pore sizes between 20 and 50 microns (Col. 17, lines 41-49). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form the pore size of the third layer of Owens and Hirschberg having dimensions between 20 and 50 microns since McCarthy teaches that these dimensions are desirable for promoting tissue ingrowth.

8. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owens (4,972,846). Owens discloses the claimed invention except for the second layer of porous PTFE having a thickness less than or equal to 10 microns. It would have been an obvious matter of design choice to form the second layer of porous PTFE to have a thickness less than or equal to 10 microns since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

9. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owens (4,972,846) in view of Hirschberg (4,573,480) as applied to claim 58. Owens and Hirschberg disclose the claimed invention except for the third layer of porous PTFE having a thickness less than or equal to 50 microns. It would have been an obvious matter of design choice to form the third layer of porous PTFE to have a thickness less than or equal to 50 microns since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

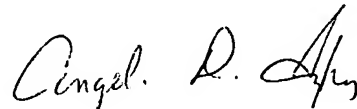
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kdm



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